



ATTORNEY DOCKET NO.: 0492611-0530 (MIT 10077)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Levenberg *et al* Examiner:
Serial No.: 10/731,672 Art Unit:
Filing Date: December 9, 2003
Title: Engineering Three-Dimensional Tissue Structures Using
Differentiating Embryonic Stem Cells

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

TRANSMITTAL LETTER

Enclosed are the following documents:

1. Form PTO-1449 (3 pages);
2. Information Disclosure Statement (6 pages);
3. Cited Art (44); and
4. Return Postcard

If any additional fees are required to be paid or if any overpayment has been made, please charge same to Deposit Account No. 03-1721.

Respectfully submitted,

Valarie B. Rosen
Registration No. 45,698

Choate, Hall & Stewart
Exchange Place
53 State Street
Boston, MA 02109
(617) 248-5000

Dated: **March 30, 2004**

3673831_1.DOC



ATTORNEY DOCKET NO.: 0492611-0530 (MIT 10077)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Levenberg *et al* Examiner:
Serial No.: 10/731,672 Art Unit:
Filing Date: December 9, 2003
Title: Engineering Three-Dimensional Tissue Structures Using
Differentiating Embryonic Stem Cells

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

STATEMENT

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, Applicant requests consideration of this Information Disclosure Statement.

Type of Statement

The present Information Disclosure Statement is:

- ☒ An *original* Information Disclosure Statement; or
☐ A *supplemental* Information Disclosure Statement.

Certificate of Mailing

I certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

March 30, 2004
Date

Susan M. Dinsmore
Signature

Susan M. Dinsmore

Typed or Printed Name of person signing certificate

Compliance with 37 CFR § 1.97

The present Information Disclosure Statement is being filed:

- ☒ Pursuant to 37 CFR § 1.97(b); no fee or certification is required:
 - ☐ Within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d);
 - ☐ Within three months of the date of entry of the national stage as set forth in § 1.491 in an international application;
 - ☒ Before the mailing of a first Office action on the merits; or
 - ☐ Before the mailing of a first Office action after the filing of a request for continued examination under § 1.114.
- ☐ Pursuant to 37 CFR § 1.97(c) after the dates listed above but before the mailing date of any of a final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application; Applicant hereby *either*:
 - ☐ Certifies that *either*:
 - ☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or
 - ☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making

reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.; or

☐ Includes herewith the fee set forth in § 1.17(p).

☐ Pursuant to 37 CFR § 1.97(d), after the mailing date of any final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application; Applicant hereby *both*:

☐ Certifies that *either*:

☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.; and

☐ Includes herewith the fee set forth in § 1.17(p).

Content of the Information Disclosure Statement

Applicant hereby makes of record in the above-identified application the reference(s) listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

Applicant includes copies of references as indicated below:

- ☒ A copy of each cited reference not indicated with an asterisk is included;
- ☐ Copies of references indicated with an asterisk on the attached form PTO-1449 are not included pursuant to 37 CFR § 1.98(d) because they were previously provided to the United States Patent Office in an Information Disclosure Statement that complies with 37 CFR § 1.98(a)-(c) and was submitted in the following patent application that is relied upon in the present case for an earlier effective filing date under 35 USC § 120:

Serial Number	Filing Date	Status

- ☐ Copies of English translations of one or more non-English references are included.

Applicant hereby makes the following additional information of record in the above-identified application:

Applicant certifies that the Information Disclosure Statement:

- ☒ Does not contain non-English language citations;
- ☐ Does contain non-English language citations, of which the following is a concise explanation; or
- ☐ Includes one or more translations of a non-English citation.

Remarks

The submission of this Information Disclosure Statement should not be construed as a representation that a search has been made.

The submission of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in § 1.56(b) .


The submission of this Information Disclosure Statement shall not be construed as a representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited patent(s) and publication(s) has (have) been fully considered by the Patent and Trademark Office during the examination of this application; and
3. The citations for the patent(s) and publication(s) be printed on any patent which issues from this application.

Notwithstanding any statements by Applicants, the Examiner is urged to form his or her own conclusions regarding the relevance of the cited reference(s).

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Valerie B. Rosen', written over a horizontal line.

Valarie B. Rosen,
Reg. No. 45,698

Dated: March 30, 2004

CHOATE, HALL & STEWART
Exchange Place
53 State Street
Boston, Massachusetts 02109
(617) 248-5000
(617) 248-4000

3669597

FORM PTO-1449 (REV. 8-83)		U.S. Department of Commerce Patent and Trademark Office		Atty. Docket: 0492611-0530 (MIT10077)		In Re Application No.: 10/731,672	
INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)				Applicant: Levenberg, et al.			
				Filing Date: December 9, 2003		Group:	
U.S. PATENT DOCUMENTS							
Examiner's Initials	U.S. Patent No.	Applicant	Issue Date		Class	Subclass	
U.S. PATENT APPLICATIONS							
Examiner's Initials:	Serial Number:	Applicant:	Publication Date:		Group:	Art Unit:	
FOREIGN PATENT DOCUMENTS							
Examiner's Initials	Document No.	Country	Date	Translation			
				Yes	No		
	WO01/88104	PCT	22 November 2001				
OTHER DOCUMENTS							
Examiner's Initials	Citation (Including Author, Title, Date, Pertinent Pages, Etc.)						
	Abe, et al., "Endoderm-Specific Gene Expression in Embryonic Stem Cells Differentiated to Embryoid Bodies", <i>Exp. Cell. Res.</i> , 229 : 27-34, 1996.						
	Allen, et al., "Epidermal Growth Factor Induces Acute Matrix Contraction and Subsequent Calpain-Modulated Relaxation", <i>Wound Repair Regen</i> , 10 : 67-76, 2002.						
	Ballermann, et al., "Shear Stress and the Endothelium", <i>Kidney Int</i> , 54 , Suppl. 67: S100-108, 1998.						
	Carter, et al., "Mechanobiology of Skeletal Regeneration", <i>Clin. Orthop</i> , (355S) : S41-S55, 1998.						
	Darland, et al., "TGF Beta is Required for the Formation of Capillary-Like Structures in Three-Dimensional Cocultures of 10T1/2 and Endothelial Cells", <i>Angiogenesis</i> , 4 : 11-20, 2001.						
	Dinsmore, et al., "Embryonic Stem Cells Differentiated in Vitro as a Novel Source of Cells for Transplantation", <i>Cell Transplant</i> , 5(2) : 131-143, 1996.						
	Donovan, et al., "The End of the Beginning for Pluripotent Stem Cells", <i>Nature</i> , 414 : 92-97, 2001.						
	Folkman, et al., "Blood Vessel Formation: What is its Molecular Basis? <i>Cell</i> , 87 : 1153-1155, 1996.						
	Freyman, et al., "Fibroblast Contractile Force is Independent of the Stiffness Which Resists the Contraction", <i>Exp. Cell Res.</i> 272 : 153-162, 2002.						
	Guan, et al., "Embryonic Stem Cell-Derived Neurogenesis. Retinoic Acid Induction and						

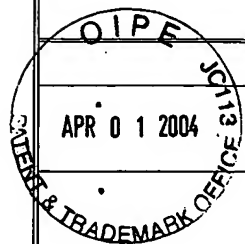
INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

Applicant: Levenberg, et al.

Filing Date:
December 9, 2003

Group:

Lineage Selection of Neuronal Cells", *Cell Tissue Res*, **305**: 171-176, 2001.Hamazaki, et al., "Heptatic Maturation in Differentiating Embryonic Stem Cells in Vitro", *FEBS Letters*, **497**: 15-19, 2001.Ingber, et al., "Mechanochemical Switching Between Growth and Differentiation During Fibroblast Growth Factor-Stimulated Angiogenesis in Vitro: Role of Extracellular Matrix", *J. Cell Biol.*, **109**: 317-330, 1989.Ito, Y., "Surface Micropatterning to Regulate Cell Functions," *Biomaterials*, **20**: 2333-2342, 1999.Johansson, et al., "Evidence for Involvement of Activin A and Bone Morphogenetic Protein 4 in Mammalian Mesoderm and Hematopoietic Development" *Mol. Cell Biol.* **15**(1): 141-151, 1995.Kaufman, et al., "Hematopoietic Colony-Forming Cells Derived From Human Embryonic Stem Cells", *Proc. Natl Acad Sci USA*, **98**(19): 10716-10721, 2001.Kaushall, et al., "Functional Small-Diameter Neovessels Created Using Endothelial Progenitor Cells Expanded *Ex Vivo*" *Nat. Med.*, **7**(9): 1035-1040, 2001.Kinner, et al., "Regulation of Smooth Muscle Actin Expression and Contraction in Adult Human Mesenchymal Stem Cells", *Exp Cell Res*, **278**: 72-83, 2002.Kleinman, et al., "Basement Membrane Complexes with Biological Activity" *Biochem.* **25**: 312-318, 1986.Lammert, et al., "Induction of Pancreatic Differentiation by Signals from Blood Vessels", *Science*, **294**: 564-567, 2001.Levenberg, et al., "Endothelial Cells Derived from Human Embryonic Stem Cells", *Proc. Natl. Acad. Sci. USA*, **99**(7): 4391-4396, 2002.Levinson, et al., "Embryogenesis in Vitro: Study of Differentiation of Embryonic Stem Cells", *Biol. Neonate*, **67**: 77-83, 1995.Manova, et al., "Expression of Activins and TGF Beta 1 and Beta 2 RNAs in Early Postimplantation Mouse Embryos and Uterine Decidua", *Mech Dev*, **36**: 141-152, 1992.Matsumoto, et al., "Liver Organogenesis Promoted by Endothelial Cells Prior to Vascular Function", *Science*, **294**: 559-563, 2001.Naumann, et al., "Immunochemical and Mechanical Characterization of Cartilage Subtypes in Rabbit", *J. Histochem Cytochem.*, **50**(8): 1049-1058, 2002.Niklason, et al., "Functional Arteries Grown in Vitro", *Science*, **284**: 489-493, 1999.Ninomiya, et al., "Endoderm Differentiation and Inductive Effect of Activin-Treated Ectoderm in Xenopus", *Dev Growth Differ.*, **41**: 391-400, 1999.Nomi, et al., "Principals of Neovascularization for Tissue Engineering", *Mol. Aspects Med.*, **23**: 463-483, 2002.Odorico, et al., "Multilineage Differentiation from Human Embryonic Stem Cell Lines", *Stem Cells*, **19**: 193-204, 2001.

(REV. 8-83)

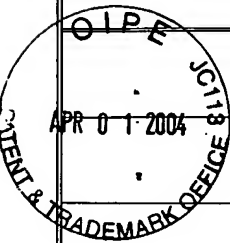
INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

Applicant: Levenberg, et al.

Filing Date:
December 9, 2003

Group:



Offield, et al., "PDX-1 is Required for Pancreatic Outgrowth and Differentiation of the Rostral Duodenum", *Development*, **122**: 983-995, 1996.

Pegoretti, et al., "In Vitro Degradation of Poly(L-Lactic Acid) Fibers Produced by Melt Spinning", *J. Appl. Polym. Sci.*, **64**: 213-223, 1997.

Risau, et al., "Vasculogenesis", *Annu. Rev. Cell. Dev. Biol.*, **11**: 73-91, 1995.

Schuldiner, et al., "Effects of Eight Growth Factors on the Differentiation of Cells Derived from Human Embryonic Stem Cells", *Proc. Natl. Acad. Sci. USA*, **97**(21): 11307-11312, 2000.

Semler, et al., "Mechanochemical Manipulation of Hepatocyte Aggregation can Selectively Induce or Repress Liver-Specific Function", *Biotechnol Bioeng.* **69**(4): 359-369, 2000.

Semler, et al., "Engineering Hepatocyte Functional Fate through Growth Factor Dynamics: The Role of Cell Morphologic Priming", *Biotechnol Bioeng.*, **75**(5): 510-520, 2001.

Smith, "Identification of a Potent Xenopus Mesoderm-Inducing Factor as a Homologue of Activin A", *Nature*, **345**: 729-731, 1990.

Stocum, D.L. "Stem Cells in Regenerative Biology and Medicine", *Wound Repair Regen.*, **9**: 429-442, 2001.

Taub, et al., "Epidermal Growth Factor or Transforming Growth Factor α is Required for Kidney Tubulogenesis in Matrigel Cultures in Serum-Free Medium", *Proc. Natl. Acad. Sci. USA*, **87**(10): 4002-4006, 1990.

Thomson, et al., "Embryonic Stem Cell Lines Derived from Human Blastocysts", *Science*, **282**: 1145-1147, 1998.

Tiedemann, et al., "Pluripotent Cells(Stem Cells) and Their Determination and Differentiation in Early Vertebrate Embryogenesis", *Dev. Growth Differ.*, **43**: 469-502, 2001.

Vacanti, et al., "Selective Cell Transplantation Using Bioabsorbable Artificial Polymers as Matrices", *Journal of Pediatric Surgery*, **23**(1): 3-9, 1988.

Vukicevic, et al., "Identification of Multiple Active Growth Factors in Basement Membrane Matrigel Suggests Caution in Interpretation of Cellular Activity Related to Extracellular Matrix Components", *Exp. Cell Res.* **202**: 1-8, 1992.

Wobus, A.M., "Potential of Embryonic Stem Cells", *Mol Aspects Med*, **22**: 149-164, 2001.

Zaleskas, et al., "Growth Factor Regulation of Smooth Muscle Actin Expression and Contraction of Human Articular Chondrocytes and Meniscal Cells in a Collagen-GAG Matrix", *Exp Cell Res.*, **270**: 21-31, 2001.

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.